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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/347,064 07/02/99 ECK

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ONE COMMERCE SQUARE
2005 MARKET STREET SUITE 2200
PHILADELPHIA PA 19103

EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

01/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/347,064

Applicant(s)
Eck et al.

Examiner
Gerald Ewoldt

Group Art Unit
1644



☒ Responsive to communication(s) filed on Nov 27, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-46 is/are pending in the application.

Of the above, claim(s) 28, 30, 31, and 38-46 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-27, 29, and 32-37 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-27, 29, and 32-37 are being acted upon. Note that claim 32 is being examined only as it pertains to a nucleic acid.
2. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
3. Claims 32-33 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility, for the reasons of record set forth on Paper No. 9, mailed 5/24/00.
4. Claims 32-33 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation. Enablement is considered in view of the *Wands* factors (MPEP 2164.01 (a)) for the reasons of record set forth on Paper No. 9, mailed 5/24/00.

Applicant's arguments, filed 11/27/00, have been fully considered but have not been found convincing. Applicant argues that the nucleic acids of the instant claims have an apparent, well-established, asserted, specific, substantial, and credible utility as a medicament and a kit. The Examiner disagrees, see 3. and 4., *supra*.

Applicant argues that it is inappropriate for the Examiner to concentrate too intently on methods of treatment, i.e., consider the enablement of the medicament and kit of the instant claims in light of their intended use. However, if a product is not enabled for its intended use, one skilled in the art would not know how to use the product, thus the product would not be allowable under the first paragraph of 35 U.S.C. 112.

Applicant argues the *Wands* factors individually:

Nature of the invention: Applicant argues that page 27, lines 11-24 provide support for the use of the claimed kit. However, said lines are silent as to a kit.

Breadth of claims: Applicant argues that the method of using the medicament and kit of the instant claims is sufficiently enabled for "a variety of disease states" (this argument indicates that the kit is indeed intended to comprise a medicament). However, the Examiner finds the disclosure of the specification insufficient to support the use of the claimed medicament in conjunction with any disease state.

State of the prior art: Applicant argues that the claimed medicament and kit need not work well, at an intermediate level, or even poorly. The specification, however, provides insufficient support to show that the claimed medicament and kit have any efficacy towards any disease state whatsoever. Further, the Examiner in no way indicates that gene therapy methods work (as Applicant seems to believe), but do not work well. The Anderson quote, *supra*, clearly indicates that there existed at the time of the invention no conclusive evidence to support successful methods of gene therapy. See Examiner's comments regarding the claimed kit, *supra*.

Working Examples and Guidance in the specification: Applicant argues that Examples 1-6 support the claimed kit. However, the claimed kit is not disclosed in any of the examples. Applicant further argues that Applicant need only teach how to use the claimed invention. It is precisely the Examiner's opinion, however, that the specification is insufficient to teach how to use the claimed invention.

Predictability of the art: Applicant argues that the skilled artisan would not believe the claimed vectors to be inoperable. However, the Examiner does find the claims to a medicament and kit sufficiently supported by the specification, i.e., Applicant has not demonstrated a sufficient degree of efficacy for the claimed invention.

Amount of experimentation necessary: Applicant merely reiterates the previous arguments and "crudely" summarizes the invention. Applicant is silent as to the amount of experimentation necessary to use the invention as claimed.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-27, 29, and 34-37 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a fusion protein consisting of:

- A) an effector module consisting of SEQ ID NO:1,
- B) a processing module consisting of SEQ ID NO:5,
- C) a targeting module consisting of bFGF,
- D) a modulating module consisting of SEQ ID NO:3,
- E) an affinity module consisting of SEQ ID NO 17,

does not reasonably provide enablement for nucleic acids encoding fusion protein fragments and derivatives thereof, or nucleic acids encoding fusion proteins containing amino acid deletions, substitutions, insertions, additions, or exchanges. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons of record set forth on Paper No. 9, mailed 5/24/00.

Applicant's arguments, filed 11/27/00, have been fully considered but have not been found convincing. Applicant misrepresents the wording of the rejection in that Applicant asserts that "the Examiner incorrectly asserts that the specification fails to reveal the specific properties of functional effector, processing, modulating, targeting, and affinity modules." The Office action actually states "The specification fails to provide sufficient guidance regarding the specific properties required to determine whether a polypeptide encoded by the claimed nucleic acid is a functional effector, processing, modulating, targeting, or affinity module," a position the Examiner maintains. Applicant further argues that the specification need not provide guidance as to how to predict the functionality of any particular fragment or derivative. The Examiner disagrees. Applicant further argues that the glycosylation state of the proteins encoded by the claimed nucleic acids is irrelevant and that the specification clearly discloses that the fusion protein can be produced in eukaryotic cells. However, all examples in the specification disclose non-glycosylated (*E. coli*) fusion proteins exclusively. Further, the specification merely asserts that a glycosylated (eukaryotic) fusion protein would function.

9. Claims 1-27, 29, and 32-37 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention for the reasons of record set forth on Paper No. 9, mailed 5/24/00.

Applicant's arguments, filed 11/27/00, have been fully considered but have not been found convincing. Applicant argues that "possession" of the claimed invention merely requires "conception" of the invention and that the disclosure constitutes a sufficient written description of the invention as claimed. However, it is the opinion of the Examiner that, given the virtually unlimited scope of the claims, Applicant has not sufficiently demonstrated even the conception of all possible embodiments encompassed by the broad claims.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 5, 8, 10-11, 13-14, 16, 34, and 36 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record set forth on Paper No. 9, mailed 5/24/00.

Applicant's arguments, filed 11/27/00, have been fully considered but have not been found convincing. Applicant argues that "degenerate", "a cell of the specific immune system", "a cell of the unspecific immune system", "a degenerate cell of the immune system", "/" and the moiety "S1'", while undefined in the specification, would be understood by the skilled artisan. While the terms may have vaguely defined meanings within the art, said terms are still ambiguous and render the claims indefinite.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-6, 8-14, 16-27, 29, and 34-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0751221A1 (1997, IDS) in view of Lappi et al. (1994, of record) for the reasons set forth in Paper No. 9, mailed 5/24/00.

Applicant's arguments, filed 11/27/00, have been fully considered but have not been found convincing. Applicant argues that the priority date of the instant Application is the priority date of PCT/EP98/00009, 1/97 (which is also the publication date of EP 0751221A1). However, no certified copies of the priority documents nor any translation of non-English priority documents have been received, thus priority has not been granted.

14. Claims 7 and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0751221A1 (of record) in view of Lappi et al. (of record) as applied to claims 1-6, 8-14, 16-27, 29, and 32-37 above, and further in view of Grisshammer et al. (1995, of record) for the reasons set forth in Paper No. 9, mailed 5/24/00.

Applicant's arguments, filed 11/27/00, have been fully considered but have not been found convincing. Applicant argues that the priority date of the instant Application is the priority date of PCT/EP98/00009, 1/97 (which is also the publication date of EP 0751221A1). However, no certified copies of the priority documents nor any translation of non-English priority documents have been received, thus priority has not been granted.

15. The following are New Grounds of Rejection necessitated by Applicant's amendment, filed 11/27/00.

16. Claims 8 and 26, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- A) "..., and S1' is any amino acid residue." (Claim 8),
- B) "species" (added three times) (Claim 26).

Applicant's amendment, filed 11/27/00, asserts that no new matter has been added. However, the amended terms are not disclosed in the original specification or claims as filed.


17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
January 22, 2001


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600